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Research Paper

Cost Utility Analysis of Cervical Therapeutic Medial Branch Blocks in Managing Chronic Neck Pain

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Abstract

Background: Controlled diagnostic studies have established the prevalence of cervical facet joint pain to range from 36% to 67% based on the criterion standard of $\geq 80\%$ pain relief. Treatment of cervical facet joint pain has been described with Level II evidence of effectiveness for therapeutic facet joint nerve blocks and radiofrequency neurotomy and with no significant evidence for intraarticular injections. However, there have not been any cost effectiveness or cost utility analysis studies performed in managing chronic neck pain with or without headaches with cervical facet joint interventions.

Study Design: Cost utility analysis based on the results of a double-blind, randomized, controlled trial of cervical therapeutic medial branch blocks in managing chronic neck pain.

Objectives: To assess cost utility of therapeutic cervical medial branch blocks in managing chronic neck pain.

Methods: A randomized trial was conducted in a specialty referral private practice interventional pain management center in the United States. This trial assessed the clinical effectiveness of therapeutic cervical medial branch blocks with or without steroids for an established diagnosis of cervical facet joint pain by means of controlled diagnostic blocks. Cost utility analysis was performed with direct payment data for the procedures for a total of 120 patients over a period of 2 years from this trial based on reimbursement rates of 2016. The payment data provided direct procedural costs without inclusion of drug treatments. An additional 40% was added to procedural costs with multiplication of a factor of 1.67 to provide estimated total costs including direct and indirect costs, based on highly regarded surgical literature. Outcome measures included significant improvement defined as at least a 50% improvement with reduction in pain and disability status with a combined 50% or more reduction in pain in Neck Disability Index (NDI) scores.

Results: The results showed direct procedural costs per one-year improvement in quality adjusted life year (QALY) of United States Dollar (USD) of \$2,552, and overall costs of USD \$4,261. Overall, each patient on average received 5.7 ± 2.2 procedures over a period of 2 years. Average significant improvement per procedure was 15.6 ± 12.3 weeks and average significant improvement in 2 years per patient was 86.0 ± 24.6 weeks.

Limitations: The limitations of this cost utility analysis are that data are based on a single center evaluation. Only costs of therapeutic interventional procedures and physician visits were included, with extrapolation of indirect costs.

Conclusion: The cost utility analysis of therapeutic cervical medial branch blocks in the treatment of chronic neck pain non-responsive to conservative management demonstrated clinical effectiveness and cost utility at USD \$4,261 per one year of QALY.

Key words: Chronic neck pain, cervical facet joint pain, cervical medial branch blocks, controlled diagnostic blocks, cost utility analysis, cost effectiveness analysis, quality adjusted life years (QALY).

Introduction

Chronic neck pain in the general population with or without sprain or injury is common, with annual estimates of prevalence of 12.1% to 71.5% with most estimates demonstrating an annual prevalence of between 30% and 50% [1, 2]. Though less prevalent than low back pain, neck pain is the third most common chronic pain condition in the US, is expensive, may cause persistent pain, and is the fourth leading cause of disability worldwide [3, 4]. Global burden of neck pain studies and disability studies [3, 4] have revealed the prevalence of chronic neck pain in 4.9% of the population, with a significant proportion suffering with chronic neck pain with high disability. Martin *et al.* [5, 6] evaluated health care expenditures for the treatment of back and neck problems in 2005 and demonstrated that these expenditures total approximately United States Dollar (USD) \$86 billion, with an increase of 65% between 1997 and 2005 with a 49% increase in the number of patients seeking spine-related care. In addition, Dieleman *et al.* [7], in an analysis of U.S. spending on personal health care from 1996 to 2013, showed that low back and neck pain accounted for the third highest amount of health care spending in the US, with an estimated USD \$87.6 billion in 2013. They also demonstrated that spending on low back and neck pain along with diabetes mellitus increased the most over the 18 years, by an estimated USD \$57.2 billion and \$64.4 billion, respectively. Multiple diagnostic and therapeutic interventions are presently offered in managing neck pain with costs being considered as uncontrollable [8-31]. Consequently, the prevalence and disability in association with escalating costs secondary to spinal pain in general and neck pain in particular have become the focus of attention of the public-at-large, payer community, regulators, and finally, physicians and patients [3, 5-7, 32].

Neck pain may originate from intervertebral discs, facet joints, ligaments, fascia, muscles, and nerve root dura [11, 12]. The current evidence shows that the prevalence of cervical facet joint pain utilizing the criterion standard of $\geq 80\%$ pain relief to range from 36% to 67% with controlled diagnostic blocks, with a false positive rate of 27% to 63% [11, 20]. Therapeutic cervical facet joint interventions have shown Level II evidence for cervical medial branch radiofrequency neurotomy and cervical therapeutic medial branch blocks with limited evidence for intraarticular injections with best evidence synthesis [12, 20]. Thus, there continue to be significant discussions surrounding various treatment modalities used in the management of chronic neck pain. Further, these discussions are exemplified by no

demonstration of cost effectiveness or utility, increasing disability challenges, escalating utilization, diagnostic accuracy, and therapeutic effectiveness of various modalities [7, 11, 12, 20, 33-36]. Manchikanti *et al.* [8-10, 18] previously demonstrated that interventional techniques for chronic pain have increased dramatically from 2000 to 2014 with a 153% increase per 100,000 fee-for-service Medicare beneficiaries. Among these, cervical and thoracic facet joint injections increased 362.9%, and cervical and thoracic radiofrequency increased 911.5% from 2000 to 2014, per 100,000 Medicare beneficiaries [8-10, 18].

Even though multiple cost utility or effectiveness analysis studies and reviews have been published over the years in managing spinal pain [33, 35, 37-53], there are very few studies assessing the cost utility of non-surgical techniques in managing neck pain [39, 40, 50-53]. Among the interventional techniques, there are none available for neck pain. However, there have been some studies providing cost utility analysis in managing low back and lower extremity pain. Among these, spinal cord stimulation was shown to be effective compared to conventional medical management at €5,624 per quality adjusted life years (QALY) [41]. Caudal epidural injections [47] were shown to be effective at a direct procedural cost of USD \$2,173 per QALY in managing disc herniation, spinal stenosis, discogenic pain, or post surgery syndrome. In addition, percutaneous adhesiolysis [48] was demonstrated to be cost effective at a direct procedural cost of USD \$2,650 QALY in recalcitrant post-surgery syndrome and spinal stenosis. Thus, the cost utility analysis does not provide the total cost. Highly regarded surgical literature from analysis of Spine Patient Outcomes Research Trial (SPORT) trial data [45, 46] has provided a basis for estimation of indirect cost, including drug therapy. These analyses showed overall cost effectiveness of disc herniation surgery [45] at USD \$69,403 per QALY, whereas for spinal stenosis surgeries it was USD \$77,600 per QALY and USD \$115,600 per QALY for degenerative spondylolisthesis [46]. Further, these studies also showed direct costs without medication costs to be 60% for spinal stenosis, 68% for disc herniation, and 71% for degenerative spondylolisthesis with spinal stenosis with total costs of USD \$26,222, \$27,341, and \$42,081, respectively. Based on these studies considering the direct procedural costs lowest at 60% and highest indirect costs of 40%, the cost utility of caudal epidural injections is estimated to be USD \$3,628 and for percutaneous adhesiolysis, it is estimated to be USD \$4,426 per QALY with multiplication of the costs by 1.67 [47, 48]. In addition,

cost utility analysis of lumbar interlaminar epidural injections in the treatment of lumbar disc herniation, central spinal stenosis, and axial or discogenic low back pain utilizing the extrapolate method of surgical interventions of direct cost, showed an average cost of USD \$3,301 per QALY [49].

The present investigation, therefore, was undertaken to produce pragmatic, reliable, overall cost utility information for therapeutic cervical medial branch blocks in managing chronic neck pain, with or without headache and upper extremity pain, based on a previously conducted double-blind, randomized, controlled trial with a 2-year follow-up [54, 55].

Methods

Study Design

The current procedural cost utility analysis is based on a randomized controlled, double-blind trial of therapeutic cervical facet joint nerve blocks [54, 55].

Design and methodology of the trial were previously described [54, 55]. All patients in the trial had previously failed conservative treatment. After receiving 80% pain relief with controlled diagnostic blocks, they underwent therapeutic injections, either with or without steroids, in a contemporary interventional pain management setting in an ambulatory surgical center in the United States.

Analysis

The 120 patients in the trial, randomized into a group that received either local anesthetic or local anesthetic with steroids, were followed for 24 months (Fig. 1).

Reimbursement rates as of 2016, for all patients from all carriers, are the basis of costs used for both facility and physician services, due to the ever-changing nature of costs [56, 57].

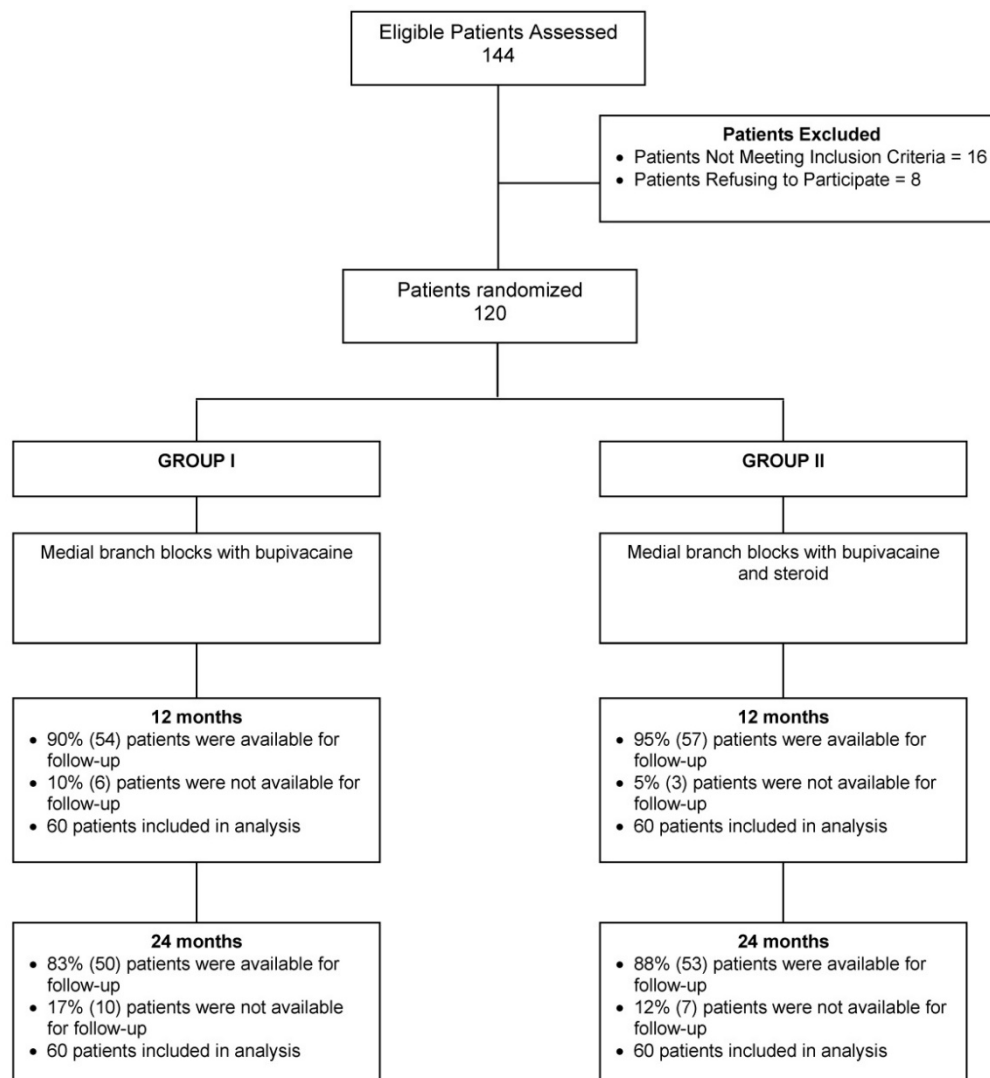


Figure 1. Schematic presentation of patient flow at 2-year follow-up for therapeutic cervical facet joint nerve blocks [54, 55].

Outcome Measures

Outcomes were measured at post-treatment 3, 6, 12, 18, and 24 months. Measurements included pain using the 11-point (0 - 10) numeric rating scale (NRS), the 0 - 50 Neck Disability Index (NDI), employment status, and opioids measured as morphine equivalents. Pain relief and disability improvement of 50% were used as improvement measures.

Cost Utility Analysis

Procedural costs for 2 years were calculated using 2016 reimbursement data for both physician and facility expenses. Quality of life improvement per year (52 weeks) for 2 years (104 weeks) was estimated based on the costs of primary outcomes of significant pain relief and improvement in function of 50% of therapeutic cervical medial branch blocks [54, 55]. The derived procedural costs were considered as direct costs without costs of drugs, constituting 60% of the overall cost based on widely held surgical studies [45, 46] and the remaining 40% was attributed to indirect costs. These costs were estimated from direct procedural cost data with multiplication by a factor of 1.67.

Extrapolation of the costs in this manuscript was based on the well-regarded cost utility analysis performed in surgical interventions of lumbar disc herniation, lumbar spinal stenosis, and lumbar spondylolisthesis from the SPORT trials [45, 46]. Tosteson *et al.* [45, 46] in detail describe their approach to calculation of direct and indirect costs, in which direct costs comprised medical and surgical costs, whereas indirect costs included productivity losses, missed days of housekeeping, and unpaid caregivers, etc. In our approach to extrapolation of these cost ratio analysis, we have also incorporated costs of medication into indirect costs. Based on this approach, with elimination of medication costs from direct costs, transferring them to indirect costs, the SPORT trials [45, 46] showed a 2-year cost of managing disc herniation of USD \$18,645 (68%), with a total cost of USD \$27,341. Similarly, for spinal stenosis and

spondylolisthesis, direct costs without medication costs were estimated to be USD \$15,717 with a total cost of USD \$26,222 or USD \$29,868 with total costs of USD \$42,081 with 60% constituting for direct medical expenses without medication for spinal stenosis and 71% apportioned to direct expense without medication for spondylolisthesis. Based on these expenses, Tosteson *et al.* [45, 46] estimated QALY for disc herniation of USD \$69,403 with 68% for direct medical costs without medical therapy, USD \$77,600 for spinal stenosis with direct medical costs of 60% and USD \$115,600 per QALY for degenerative spondylolisthesis with direct medical costs of 71%. Consequently, in this analysis, costs were attributed as 40% to indirect expenses including medical therapy and 60% to direct costs without medical therapy, with multiplication by a factor of 1.67.

The present investigation compared the unadjusted mean cost per patient. Incremental cost effectiveness analysis was not performed, as this was only one group. This was a comparative effectiveness trial with both groups yielding similar results.

Results

Patient Flow

The 120 study patients receiving therapeutic medial branch blocks were grouped based on whether they received bupivacaine only or bupivacaine with steroids. In Group I, 90% were available for follow-up at 12 months; in Group II, it was 95%. At 24 months follow-up, 83% in Group I were available for follow-up; 88% in Group II (Fig. 1).

Outcomes

Baseline demographics and clinical characteristics are shown in Table 1. Total employed were 21 patients and total unemployed were 13 patients combined in both groups. At the end of 24 months, total unemployed was reduced to 2 (data not shown in the table).

Table 1. Demographic characteristics and clinical characteristics of cervical therapeutic facet joint nerve blocks [54, 55].

		Group I (bupivacaine without steroid) (N = 60)	Group II (bupivacaine with steroid) (N = 60)	Pooled (N = 120)
Gender	Male	32% (19)	20% (12)	26% (31)
	Female	68% (41)	80% (48)	74% (89)
Age (years)	Mean ± SD	45.7 ± 13.2	42.6 ± 14.1	44.1 ± 13.7
Height (inches)	Mean ± SD	66.2 ± 3.9	65.5 ± 3.7	65.9 ± 3.8
Weight (lbs.)	Mean ± SD	177.9 ± 53.8	169.1 ± 40.8	173.5 ± 47.8
Duration of pain (months)	Mean ± SD	120 ± 122.2	87 ± 104.0	103 ± 114.2
Mode of onset of pain	Gradual	57% (34)	57% (34)	57% (68)
	Sudden	11% (7)	11% (7)	12% (14)
	WC/MVA	32% (19)	32% (19)	31% (38)

WC = Workers compensation, MVA = Motor vehicle injury

NRS and NDI data are shown in Table 2, showing baseline to 24-month improvement to be significant, but there was no significant difference with respect to the 2 groups against each other. Figure 2 reveals that 70% of all patients had a significant reduction in the NRS and NDI at 24 months.

Table 2. Pain relief and functional assessment evaluated by Neck Disability Index (NDI) characteristics with therapeutic cervical facet joint nerve blocks [54, 55].

Numeric Rating Score	Group I	Group II	Pooled
Baseline	8.2 ± 0.8	8.2 ± 1.1	8.2 ± 1.0
6 months	3.6 ± 1.1 (87%)	3.5 ± 0.7 (95%)	3.4 ± 0.9 (91%)
12 months	3.7 ± 1.2 (85%)	3.4 ± 0.9 (91%)	3.6 ± 1.0 (88%)
24 months	3.5 ± 1.0 (85%)	3.2 ± 1.0 (93%)	3.3 ± 1.0 (89%)
Neck Disability Index			
Baseline	25.4 ± 5.9	25.1 ± 5.0	25.3 ± 5.5
6 months	12.2 ± 5.9 (78%)	11.6 ± 4.2 (88%)	11.9 ± 5.1 (83%)
12 months	11.9 ± 5.4 (85%)	11.7 ± 4.5 (85%)	11.8 ± 5.0 (85%)
24 months	11.5 ± 5.1 (85%)	11.0 ± 4.7 (90%)	11.2 ± 4.9 (87%)

(—) illustrates proportion with significant pain relief (≥ 50%) from baseline

Adverse Events

Due to lack of adverse events reported among study participants in the investigation, no costs related to adverse events were incurred.

Cost Utility Analysis

In this analysis, cost for procedure, overall cost, and cost for improvement in quality of life were assessed based on the quality of life improvement as shown in Table 3. Average total cost per patient in 2 years was also assessed.

As shown in Table 3, total direct costs without medical therapy for 2 years were USD \$4,222.08. The total direct costs for one year of improvement of

quality of life were USD \$2,551.65. Whereas, with extrapolation of indirect costs with the addition of 40% costs, overall costs were estimated to be USD \$4,261.

Discussion

The cost utility analysis of therapeutic cervical medial branch blocks in chronic persistent neck pain in patients who failed to respond to conservative management, with inclusion of 120 patients with a 2-year follow-up showed QALY of USD \$2,552 for direct procedural costs without inclusion of drug costs. The overall costs with direct and indirect costs were estimated to be USD \$4,261 per QALY. Both groups of patients with or without steroids with bupivacaine showed similar results. There was significant improvement from baseline in the majority of patients.

In this analysis, current reimbursement data of 2016 was utilized from all carriers for all patients, related to changes in coverage policies and reimbursement payments and inflation [56, 57]. Due to multiple patients having undergone bilateral procedures and facet joint nerve blocks always involved at least 2 levels, average overall cost per patient was higher than in our previous cost utility studies of caudal epidural injections [47] and lumbar interlaminar epidural injections [49], but was similar or somewhat less than percutaneous adhesiolysis [48] of USD \$3,628, USD \$3,301 and USD \$4,426, respectively. The only difference between the groups was there were no diagnostic blocks performed with caudal epidural injections. Diagnostic nerve blocks for cervical facet joint nerve blocks were not included in this analysis. Similarly, in percutaneous adhesiolysis in managing post lumbar surgery syndrome and lumbar central spinal stenosis, the prior cost of epidural injections or outcomes were also not included.

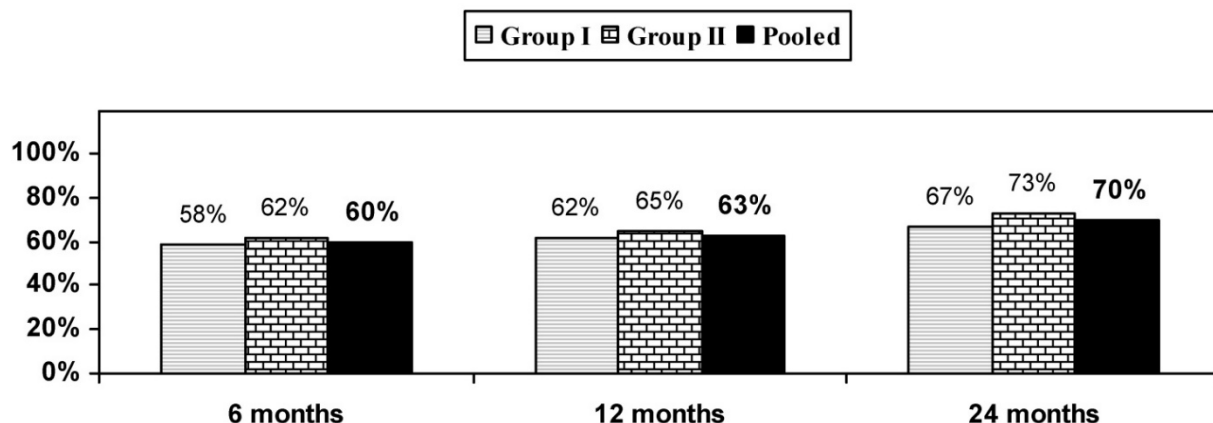


Figure 2. Proportion of patients with significant reduction in Numeric Rating Score (NRS) and Neck Disability Index (NDI) (≥ 50% reduction from baseline) with therapeutic cervical facet joint nerve blocks.

Table 3. Analysis of cost effectiveness of cervical therapeutic medial branch nerve blocks in managing chronic pain (USD \$).

	Group I (bupivacaine without steroid)	Group II (bupivacaine with steroid)	Pooled
Number of patients	60	60	120
Total number of procedures for 2 years	342	344	686
Number of treatments for 2 years per patient (mean) \pm SD	5.7 \pm 2.4	5.7 \pm 2.1	5.7 \pm 2.2
Number of weeks with significant improvement for all patients in the study in weeks	4999	5326	10325
Significant improvement in two years per patient (mean) \pm SD	83.3 \pm 27.4	88.8 \pm 21.1	86.0 \pm 24.6
Significant improvement in weeks per procedure (mean) \pm SD	15.0 \pm 12.31	16.1 \pm 14.1	15.6 \pm 12.3
Total Cost USD (\$)			
Physician	\$66,652.26	\$72,340.20	\$138,992.46
Facility	\$179,037.97	\$188,619.19	\$367,657.16
Total	\$245,690.23	\$260,959.38	\$506,649.61
Cost per procedure USD (\$)			
Physician	\$194.89	\$210.29	\$202.61
Facility	\$523.50	\$548.31	\$535.94
Total	\$718.39	\$758.60	\$738.56
Direct total costs per patient for two years USD (\$)	\$4,094.84	\$4,349.32	\$4,222.08
Direct procedural costs without medical therapy for 1-year improvement in quality of life USD (\$)	\$2,555.69	\$2,547.86	\$2,551.65
Indirect costs including drugs USD (\$) for one-year improvement of life	\$1,712.31	\$1,707.06	\$1,709.60
Total estimated cost USD (\$) including procedural costs, drug costs, and indirect costs for one-year improvement in quality of life	\$4,268.00	\$4,254.92	\$4,261.25

The purpose of cost utility analysis in health economics is to estimate the ratio between the cost of a health-related intervention and the benefit it produces in terms of number of years lived in full health by the beneficiaries. Therefore, it can be considered as a special case of cost effectiveness analysis, and both the terms are often used interchangeably. Consequently, in this scenario, cost is measured in monetary units, unlike cost-benefit analysis, in which benefits do not have to be expressed in monetary terms. Among the studies assessing cost effectiveness of various treatments in managing chronic neck pain [33, 35, 40, 50-53], one study assessed [33] patient centered quality of life and health economics based on surgery for degenerative cervical myelopathy. A second study [35] evaluated the effect of obesity on cost per QALYs gained following anterior cervical discectomy and fusion in elective degenerative pathology. Witiw et al [33] showed mean QALY gained over the 24-month study period was 0.139 and the mean 2 years cost of treatment was Canadian (CAN) \$19,217 \pm CAN \$12,404, with cost associated with operation comprising 65.7% of the total. They estimated lifetime incremental cost-to-utility ratios of surgical intervention of CAN \$20,547 per QALY gained. Among the studies assessing nonsurgical treatments [40, 50, 51], Leininger *et al.* [50] showed that inflation adjusted costs of home exercise and advice with addition of spinal manipulative therapy would result in inflation adjusted to 2014 USD \$65,731 per QALY gained. All other assessments showed improvements in the QALY, but without cost per QALY determined.

Among earlier publications, Kepler *et al* [37] showed that one-year cost of QALY gained was less than USD \$100,000 in only 45% of the studies assessed. Similarly, Indrakanti *et al.* [38] showed that a greater value was placed on studies of non-operative treatments compared to surgical treatments. Yet, in another systematic review, Dagenais *et al.* [39] showed highly variable costs for QALY ranging from USD \$304 to USD \$579,527, with a median cost of USD \$13,000.

Among the interventional techniques, Taylor *et al.* [41] illustrated the cost effectiveness for spinal cord stimulation based on NICE criteria [58] at a cost of £5,624 per QALY. In contrast, Kumar and Rizvi [43], in an assessment of cost effectiveness of spinal cord stimulation therapy in management of chronic pain of failed back surgery syndrome, complex regional pain syndrome, peripheral arterial disease, and refractory angina pectoris, showed 2010 CAN \$9,293 CAN \$11,216, CAN \$9,350, and CAN \$9,984 for failed back surgery syndrome, complex regional pain syndrome, peripheral arterial disease, and refractory angina pectoris, respectively, per QALY gained. Overall cost utility analysis of caudal epidural injections, lumbar interlaminar epidural injections, and percutaneous adhesiolysis yielded favorable results in managing chronic low back pain of various pathologies [45-49]. Manchikanti *et al.* [47] performed a cost utility analysis of caudal epidural injections in the treatment of lumbar disc herniation, axial or discogenic low back pain, central spinal stenosis, and post lumbar surgery syndrome showing average direct procedure

costs per one-year QALY of USD \$2,173 and USD \$3,628 of overall costs. Even though this study was limited to a single center, it included 480 patients in the analysis and data were derived from 4 separate randomized controlled trials (RCTs). Similarly, cost utility analysis of percutaneous adhesiolysis in managing pain of post lumbar surgery syndrome and lumbar central spinal stenosis was performed in a total of 130 patients after failure to response to caudal epidural injections from 2 RCTs from a single center showing direct procedural cost utility for one-year QALY of USD \$2,650 and overall cost of USD \$4,426 [48]. Manchikanti *et al.* [47] performed a cost utility analysis of lumbar interlaminar epidural injections with or without steroids in the treatment of lumbar disc herniation, central spinal stenosis, and discogenic or axial low back pain with data derived from 3 RCTs [59-61] that included a 2-year follow-up, with inclusion of 360 patients in this analysis. The methodology described in this manuscript was utilized with multiplication of procedural costs without medical therapy by a factor of 1.67 with overall cost per QALY of USD \$3,301 with direct costs of USD \$1,977, somewhat less than caudal epidural injections and significantly less than cost utility of cervical therapeutic medial branch blocks in managing chronic neck pain described in this manuscript.

Furlan *et al.* [40], in a systematic review and meta-analysis of efficacy, cost effectiveness, and safety of selected complementary and alternative medicine therapies for neck and low back pain, showed that alternative medicine treatments did not significantly reduce disability compared to sham, yielding mixed results. In this analysis, they included spinal manipulation in 2 studies assessing neck pain, massage in 3 studies, and acupuncture in one study. Acupuncture for neck pain was associated with significantly higher total cost compared to usual care (€1,565 vs. €1,496) with €12,469 per QALY gained in patients with chronic neck pain [52].

Driessen *et al.* [51], in another systematic review of conservative treatments for neck pain and cost effectiveness, showed that only 5 economic evaluations met inclusion criteria. In their analysis, one study [53] comparing manual therapy plus advice and exercise compared to advice and exercise showed £34,000 per QALY threshold. Leininger *et al.* [50] showed cost effectiveness of spinal manipulative therapy, supervised exercise, and home exercise for older adults with chronic neck pain. They showed the inflation-adjusted cost in 2014 USD \$65,731 per QALY gained, which was below the World Health Organization's recommended threshold, based on 3 times the 2014 per capita GDP of USD \$163,889.

Costs of surgical interventions are considered to be the highest in managing spinal pain [33, 35, 45, 46]. Cost effectiveness analysis of posterior cervical fusion in the cervical spine showed USD \$20,547 per QALY in one study [34]; whereas, in another study [35], cost utility of anterior cervical discectomy and fusion in obese patients were USD \$52,816 per QALY.

Cost utility analysis has emerged over the years as an important tool in provision of value-based health care by merging patient-centered outcomes with utilization of health care resources [35, 59, 61, 62-64]. A cost utility analysis is a type of cost effectiveness analysis that examines the costs and effectiveness of interventions by employing the QALY as its measure of effectiveness. Essentially, cost utility analysis examines the effects of interventions on both quantity and quality of life and are considered as the standard for reporting of cost effectiveness analysis and allow policymakers and providers to compare treatment strategies among different disciplines and identify the relative priorities for optimal resource allocation among various interventions [35, 43, 65, 66]. Numerous studies have analyzed the cost effectiveness of various cervical spine interventions [33, 35, 40, 50, 51, 52, 53, 67, 68]. A multitude of these analyses revealed highly variable costs for conservative management, as well as surgical management of cervical disorders. Consequently, the present assessment is the first assessment ever performed for interventional techniques in managing chronic neck pain, specifically with therapeutic facet joint nerve blocks.

Indirect costs are generally not considered in health technology assessment [69-71]. In addition, based on the Affordable Care Act (ACA), cost effectiveness is not utilized as a basis for coverage or other analysis in the US [70-74]. However, cost effectiveness and cost utility analysis are frequently utilized as a basis for coverage in other countries including the United Kingdom [58]. These assessments are based on health technology assessment guidance. Despite the fact that the US does not openly consider cost utility analysis for coverage, the importance of high quality with low expense has been stressed with numerous public policy decisions including the ACA, physician quality reporting systems, value-based payment systems, merit-based incentive payment systems, and accountable interventional pain management [70-85].

Multiple advantages of this study include the data derived from an RCT of 120 patients [54, 55] making it the first and only cost utility analysis from an RCT. In addition, it has been recommended that cost effectiveness models should make use of data on absolute pain including baseline pain, routinely

collected in trials, to inform model health-related quality of life outcomes [69]. Critchlow *et al.* [69] strongly recommended that absolute pain categories from 11-point NRS data are used to capture key pain outcomes. We also provided transparent data for all insurers for physician and operating room services. Further, this analysis also provides a pragmatic approach as it was performed in a practical, non-academic setting, despite utilizing strict parameters of diagnosis and therapy. Direct procedural cost utility analysis of USD \$2,552 and overall costs of USD \$4,261 per QALY is below the majority of modalities described thus far and well below the incremental cost effectiveness ratio of less than £20,000 per year QALY as recommended by NICE [58]. Consequently, the cervical medial branch blocks performed as described in this RCT meet the criteria for inclusion based on NICE criteria and cost utility analysis criteria in all countries.

The limitations of this analysis are based on the fact that only current expenses in the therapeutic phase were included. In this regard, only physician and facility costs were utilized instead of analysis in various other settings, as well as other modalities utilized in conjunction with therapeutic facet joint nerve blocks (extrapolated with multiplication of a factor 1.67 of direct procedural costs), as well as the cost of the diagnostic nerve blocks. However, the benefits of returning to work, also have not been analyzed.

Utilization of diagnostic blocks also may increase the cost for 2 procedures at a cost of USD \$740 to USD \$1,550 for each patient, but with addition of 9 to 10 weeks of significant improvement, which may reduce one procedure, thus adding less than USD \$500 per QALY. In addition, use of payments from 2016 may also be criticized; however, it is essential to use the current and realistic payment rates based on dynamic changes in payment policies. In fact, there have been significant reductions in Medicare payments and those by other carriers in 2017. Consequently, utilizing 2017 data may even further reduce the cost of the procedures performed.

Overall, the cost utility analysis of this assessment based on the reimbursement for physician and facility charges in an ambulatory surgery center in a contemporary interventional pain management setting, utilizing the current data, may not apply to all settings. Further, all the patients underwent 80% pain relief as the criterion standard for inclusion in the therapeutic phase. It may be argued that radiofrequency neurotomy may be more cost effective since it provides longer-term relief [12, 13, 20]; however, there have not been any cost estimations available for cervical radiofrequency neurotomy.

Further, with expected improvement with radiofrequency of 6 months with a single treatment, and twice the costs of procedures, costs may be similar. However, as many patients presented with bilateral pain requiring bilateral therapeutic facet joint nerve blocks incorporated into this cost utility analysis, twice the number of procedures may be required with radiofrequency neurotomy as procedures are performed only on one side, increasing the potential costs and reducing cost utility value.

These costs are only applicable for procedures performed in an ambulatory surgery setting with sterile operating room [56, 57]. Consequently, it is estimated that costs of this analysis overall may be approximately 30% to 70% higher in a hospital setting and approximately 20% to 30% lower compared to an in-office setting [56, 57].

Conclusion

In the present investigation, the cost utility analysis of therapeutic facet joint nerve blocks in the treatment of chronic recalcitrant neck pain with or without headache and upper extremity pain shows cost utility of direct procedural cost of USD \$2,552 per QALY and overall cost utility of USD \$4,261 per QALY.

Abbreviations

QALY: quality-adjusted life year; ACA: Affordable Care Act; USD: United States Dollar; CAN: Canadian; IRB: Institutional Review Board; NRS: numeric rating scale; NDI: Neck Disability Index; RCTs: randomized controlled trials

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Competing Interests

Dr. Manchikanti has provided limited consulting services to Semnur Pharmaceuticals, Incorporated, which is developing nonparticulate steroids. Dr. Kaye is a speaker for Depomed and Merck, Inc. Dr. Hirsch is a consultant for Medtronic.

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